DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 10, 2014

Haag-Streit AG
% Ms. Dawn Tibodeau
Third Party 510(k) Project Coordinator
TUV SUD America, Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

Re: K142423
Trade/Device Name: EyeSuite Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: NFJ
Dated: August 26, 2014
Received: August 28, 2014

Dear Ms. Tibodeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
EyeSuite Imaging

Indications for Use *(Describe)*
EyeSuite Imaging is a software program intended for use for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentational ophthalmic images and videos, acquired from computerized diagnostic instruments, through direct connection or through networks.

EyeSuite Basic is a patient and examination management system, acting as a base and communication platform for other EyeSuite software components.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Chapter 5: 510(k) Summary

1. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

2. Submitter of this Pre-Market Notification:

Haag-Streit AG
Gartenstadtstrasse 10
3098 Koeniz / Switzerland
Telephone: +41 31 978 01 11
Facsimile: +41 31 978 02 82

Establishment Registration Number: 1000176188

Contact Person:
Oscar Banz
Head of Quality Management & Regulatory Affairs
Telephone: +41 31 978 01 48
Facsimile: +41 31 978 02 82
E-mail: oscar.banz@haag-streit.com

This summary was prepared on August 11, 2014

3. Trade Name of the Device

EyeSuite Imaging

4. Common / Usual Name

Picture archiving and communications system

5. Classification Name

Device Classification Name:	System, Image Management, Ophthalmic
Regulation Medical Specialty:	Ophthalmic
Review Panel:	86 - Ophthalmic
Product Code:	NFJ
Regulation number:	21 CFR 892.2050 - Picture archiving and communications system
Device Class:	Class II

6. Predicate Devices

Trade / Device Name:	Nidek Advanced Vision Information System (NAVIS)
Applicant:	NIDEK, Inc., 21911 Erie Ln., Lake Forest, CA 92630
510(k) Premarket Notification number:	K013694
Device Class:	Class II
Product Code:	NFJ
Regulation Number:	21 CFR 892.2050 - Picture archiving and communications system

Trade / Device Name:	IMAGEnet Professional PC Software System
Applicant:	TOPCON Corp., 310 Terrace Avenue, Suite 201, Cincinnati OH 45220
510(k) Premarket Notification number:	K082364
Device Class:	Class II
Product Code:	NFJ
Regulation Number:	21 CFR 892.2050 - Picture archiving and communications system

7. General Device Description

EyeSuite Imaging is a software used by eye care professionals together with imaging systems on Haag-Streit slit lamps or other devices. EyeSuite Imaging requires a computer running Microsoft Windows in one of the following versions:

- Windows XP, SP3 (32 Bit)
- Windows Vista, SP2 (32 and 64 Bit)
- Windows 7, SP1 (32 and 64 Bit)
- Windows 8 and 8.1 (32 and 64 Bit)

A slit lamp is an instrument consisting of a light source that can be focused to shine a thin sheet of light into the eye. It is used in conjunction with a biomicroscope. The lamp facilitates an examination of the anterior segment, or frontal structures and posterior segment, of the human eye. With an imaging system a two dimensional image or video of what is seen through the biomicroscope can be recorded into widely used data formats, such as TIFF or JPEG in case of still images or MJPEG in case of a video. These records can be used for documentational purpose or to explain findings to the patient. It is optionally possible to connect the software to a DICOM PACS for storing the recorded image data.

EyeSuite Imaging allows the user to control the Haag-Streit imaging devices attached to the slit lamp or other devices, enables recording of images or videos, allows to view, modify and store the results together with accompanying information such as patient data, information on camera settings or notes of the examiner. The examiner may also highlight significant image features by using the provided draw and measure tools that allow to add predefined overlays, pixel measurements or angle measurements in the image plane. The software is not able and not intended to provide any diagnosis, but it helps the user to examine the visible structures of the eye and enables him to present and store his findings.

EyeSuite Imaging is a software application which is part of the Haag-Streit EyeSuite software product family that is licensed to customers of Haag-Streit Imaging devices. All imaging data acquisition, processing or consistency-check related features are provided by the EyeSuite Imaging Extension component and the EyeSuite Imaging Viewer component. Standard elements such as user management, patient management, database connections, basic settings, installation and backup routines are provided by the EyeSuite Basic component. The architectural decision of isolating standard features into the EyeSuite Basic component was made to reuse these features in other EyeSuite software products.

The imaging modules supported by EyeSuite Imaging are the Haag-Streit IM900 and the Haag-Streit CM900. The EyeSuite Imaging software allows to take control of camera features such as exposure time, camera gain or white balance settings. The release modules supported by EyeSuite Imaging are the Haag-Streit RM01, the Haag-Streit RMX01 and the Haag-Streit Footswitch. These supplementary devices are registered accessory parts to the class II slit lamp microscope (FDA clearance number K100202).

The recommendations of the following guidance were addressed: Guidance for the Submission Of Premarket Notifications for Medical Image Management Devices - Document issued on: July 27, 2000

8. Indications for Use

EyeSuite Imaging is a software program intended for use for controlling digital imaging devices and for acceptance, transfer, display, storage and digital processing of documentational ophthalmic images and videos, acquired from computerized diagnostic instruments, through direct connection or through networks.

EyeSuite Basic is a patient and examination management system, acting as a base and communication platform for other EyeSuite software components.

9. Comparison with Predicate Devices

It is the opinion of Haag-Streit AG that EyeSuite Imaging is substantially equivalent to the predicate devices IMAGEnet Professional PC Software System (K082364) and Nidek Advanced Vision Information System (K013694). The indications for use statement for EyeSuite Imaging is similar to the indications for use of the predicate devices cited in this application. The technological comparison demonstrates that EyeSuite Imaging is functionally equivalent to the predicate devices.

The similarities and differences between the subject device EyeSuite Imaging and the predicate devices and how these differences do not impact the safety and effectiveness of the device are provided below.

- EyeSuite Imaging and the predicate devices comprise of a central database to store patient data and diagnostic documents.
- EyeSuite Imaging and the predicate devices are capable of capturing images and videos in various formats like JPEG (lossy), TIFF (lossles) or MJPEG.
- EyeSuite Imaging and the predicate devices are capable of controlling supported camera systems and exposure parameters like signal gain, exposure time or white balance. (by default or as a separate option)
- EyeSuite Imaging and the predicate devices provide the management, storage and processing and display of patient, diagnostic, video and image data.
- EyeSuite Imaging and the predicate devices are client-server systems that provide a software application (client) to view or modify the stored data in the database (server).
- EyeSuite Imaging and the predicate devices provide a function to add text notes to medical records.
- EyeSuite Imaging and the predicate devices NAVIS (K013694) and IMAGEnet (K082364) provide a function to highlight features in images.
- EyeSuite Imaging and the predicate devices NAVIS (K013694) and IMAGEnet (K082364) provide functions to enhance image brightness, contrast and sharpness.
- EyeSuite Imaging provides the measurement functionality in pixels whereas the predicate devices NAVIS (K013694) and IMAGEnet (K082364) do measurements in mm. The measurement function in EyeSuite Imaging has been verified and validated and the results indicate that the difference in this function does not raise new questions of safety and effectiveness.
- EyeSuite Imaging and the predicate devices provide a search function to retrieve medical records linked to a specific patient.
- EyeSuite Imaging and the predicate devices include a function to export and import data.
- EyeSuite Imaging and the predicate devices can produce printouts of the stored data.
- EyeSuite Imaging and the predicate devices comprise an image compare function by displaying images side by side.

- EyeSuite Imaging and the predicate devices can connect to LAN and have DICOM interface (by default or as a separate option)

The performed evaluation of EyeSuite Imaging supports the indications for use statement and demonstrates that the device is substantially equivalent to the predicate devices. The technological characteristics of EyeSuite Imaging are similar to those of the predicate devices. In conclusion, EyeSuite Imaging shares similar technological characteristics with the predicate devices, both in terms of the manner in which images are captured, analyzed, and stored, as well as the operation of the device by the intended user.

The minor differences between EyeSuite Imaging and the predicate devices are insignificant and do not impact the safety and effectiveness of the device.

Haag-Streit believes that EyeSuite Imaging is as safe and effective as its predicate devices as it does not introduce new indications for use, raise new types of safety and effectiveness, or introduce new technology.

10. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 + Corrected version 2007-10-01 and IEC 62366:2007 to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

EyeSuite Imaging complies with voluntary standards DICOM PS 3:2011, IEC 10918-1:1994 + Technical Corrigendum 1:2005, ISO 14971:2007 + Corrected version 2007-10-01, IEC 62304:2006 and IEC 60601-1:2005 + A1:2012. Software Unit, Integration and System Testing are performed for verification and validation.

The software EyeSuite Imaging is not able and not intended to provide any diagnosis; therefore it was decided to not comply with the voluntary standard SMPTE RP 133-1991.

The device has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by trained professionals allowing sufficient review for identification ant intervention in the event of a malfunction.

11. Discussion of Nonclinical Performance Data

As the software is not able and not intended to provide any diagnosis, no nonclinical performance data was necessary to verify the safety and efficacy of the device. The software helps the user to examine the visible structures of the eye and enables him to present and store his findings.

Software validation testing and image capture testing were performed on the EyeSuite Imaging Software. Test results for the EyeSuite Imaging Software demonstrated sufficient agreement with captured images. EyeSuite Imaging was found to perform as intended. The results of performance testing and software validation testing did not raise any issues on the safety or effectiveness of the device.

- Chapter 16.9.1.19: 1182_1021525_06011_Test Case 006 Capturing Imaging Data
- Chapter 16.9.1.16: 1182_1021525_03011_Test Case 003 Drawing Overlays
- Chapter 16.9.1.28: 1182_1021525_17001_Test Case 017 Quantities and units
- Chapter 16.9.1.20: 1182_1021525_07011_Test Case 007 Image Evaluation

To meet the requirements of Section 514 of the Federal Food, Drug and Cosmetics Act and to demonstrate the safety and effectiveness of the software EyeSuite Imaging we have used the following FDA - recognized standards IEC 62366:2007, IEC 62304:2006 and IEC 60601-1:2005 + A1:2012. Test results for the EyeSuite Imaging Software demonstrated that the listed standards are met.

- Chapter 16.9.1.13: 1182_1021525_00021_Test Case 000 Design Verification
- Chapter 16.9.1.32: 1182_1021525_24021_Test Case 024 Instructions for Use

The EyeSuite Imaging software is DICOM PS 3:2011 compliant according to the DICOM conformance statement of the EyeSuite software package.

- Chapter 9.7: 1187_7220382_02040_DICOM Conformance Statement EyeSuite

The EyeSuite Imaging software uses JPEG compression compliant to IEC 10918-1:1994 + Technical Corrigendum 1:2005.

- Chapter 16.9.1.044: 1183_1021526_40001_Test Case U40 DefaultUtilsJPEG

12. Discussion of Clinical Performance Data

As the software is not able and not intended to provide any diagnosis, no clinical performance data was necessary to verify the safety and efficacy of the device. The software helps the user to examine the visible structures of the eye and enables him to present and store his findings.

13. Conclusions

The software EyeSuite Imaging has been tested and found to perform as intended.

The software has been compared to the promotional material of the predicate devices, which are all legally marketed, and found to be substantially equivalent.

Therefore we conclude that the software EyeSuite Imaging is safe and effective for its intended use when used according to its Instructions for Use.